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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,225	11/07/2001	Giampiero Valleta	C36226/127436	5568

7590

07/15/2003

Bryan Cave  
245 Park Avenue  
New York, NY 10167

EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/009,225

Applicant(s)

VALLETA, GIAMPIERO

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,8-11,16-19 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-4,16-19,22-24,29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 8-11, 25-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

***Election acknowledged***

1. Applicants affirmation on the election with traverse of Group II, claims 8-11 and 25-28 is acknowledged. Traversal is requested based on the grounds that the requirement for restriction is not based on any lack of unity of invention, rather it is based on the examiner's disregard of the unity of invention. However, applicant's argument is not persuasive because lack of unity exists and is also evidenced by the documents, not based on the examiner's disregard. The claimed inventions lack the unity which exists when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In this case, the technical feature (i.e. combination of nicotinic acid(or nicotinamide) and riboflavin without any other vitamins or other inflammatory agents), is not considered to be a special technical feature, wherein the claimed technical feature is not considered to be novel in the art and also utilized in the treatment of materially different disorders as evidenced by Patrcik (US 5496827) or Blass(US 5053396). For instance, Blass(US'396) teaches a method of treating acute and/or chronic symptoms associated the excessive ingestion or inhalation if alcohols using effective amount of nicotinamide and riboflavin, see column 5, lines 28-60 and column 3, lines 5-12. Patrick also teaches a skin application that comprises administering riboflavin and methyl nicotinate together, see column 6, lines 5-10. By reviewing these references, one would

have been readily envisage the combination of nicotinic acid(or nicotinamide) and riboflavin. Thus, the claimed feature, that is a combination of nicotinic acid and riboflavin, is not considered to be a special technical feature because the reference appears to demonstrate that the claimed feature does not define a contribution which each of the inventions, considered as a whole, makes over the prior art. The argument is not persuasive because the patentably distinct inventions lack unity under PCT Rule 13.1. For the reasons mentioned immediately above, the restriction deems to be proper.

***Supplemental Election requirement***

1. Upon the election, election of species requirement is necessary to have accurate examination. This application contains claims directed to more than one species of the generic invention.

The species are as follows: pruritus, urticaria, angioedema, asthma, allergic rhinitis or allergic oculorhinitis.

The species listed above do not relate to a single general inventive concept because they are not so linked as to form a single general inventive concept under PCT Rule 13.1-3. Especially, under PCT Rule 13.2, the species lack the same or corresponding special technical features as mentioned above. Each claimed species is considered to be patentably distinct subject matter and not related to a single general inventive concept where numerous references available in the prior art demonstrate that the claimed feature does not define a contribution which each of the inventions,

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considered as a whole, makes over the prior art, see US 5627183(Urticaria Treatment), US5753213(Pruritus Tx), US 5827512(Asthma Tx), and so on.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

### ***Conclusion***

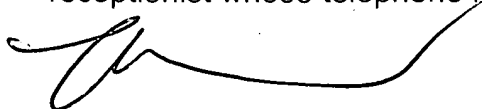
2. Although the claims that are subject to the said election requirement were previously not included in the restriction/election practice, this examiner noted that it is proper to make the election requirement if there is distinctness and independence any time before final action, even though the inventions were grouped together before. 37 CFR 1.142(a), see MPEP 811-811.04. Restriction requirement is necessary for the complete and accurate examination. Because the inventions lack the unity and the species are not related to a single general inventive concept, for the reasons set forth above, the election requirement for examination purposes as indicated is proper.

3. All the elected claims 8-11 and 25-28 are now subject to the election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel

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can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'Vickie Kim', with a long horizontal flourish extending to the right.

Vickie Kim,  
Patent examiner  
July 13, 2003  
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